May 11, 2019

Brain Sentinel, Inc.
Richard Waite
Sr. Director of Quality Assurance/Regulatory Affairs
8023 Vantage Dr., Suite 216
San Antonio, Texas 78230

Re: K182180
Trade/Device Name: SPEAC® System
Regulation Number: 21 CFR 882.1580
Regulation Name: Non-Electroencephalogram (EEG) Physiological Signal Based Seizure Monitoring System
Regulatory Class: Class II
Product Code: POS
Dated: April 10, 2019
Received: April 12, 2019

Dear Richard Waite:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Carlos L. Peña, PhD, MS
Director
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182180

Device Name
SPEAC System

Indications for Use *(Describe)*
The SPEAC® System is indicated for use as an adjunct to seizure monitoring in adults in the home or healthcare facilities during periods of rest. The System records and stores surface electromyographic (sEMG) data for subsequent review by a trained healthcare professional.

The device is to be used on the belly of the biceps muscle to analyze sEMG signals that may be associated with generalized tonic-clonic (GTC) seizures. When sEMG signal patterns associated with a unilateral, appendicular, tonic extension that could be associated with a GTC seizure are detected, the SPEAC System sends adjunctive alarms to alert caregivers. Adjunctive alarms may be disabled by a physician order while continuing to record sEMG data for subsequent review.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K182180
Traditional 510(k) Summary

Date Prepared May 10, 2019

Submitter Brain Sentinel, Inc
8023 Vantage Drive, Suite 216
San Antonio, TX 78230
(210) 951-8681

Contact Person Richard Waite, Sr.
Director of Quality Assurance/Regulatory Affairs
Brain Sentinel, Inc
(214) 662-9277
Richard.Waite@brainsentinel.com

Subject Device K182180

Device Name	SPEAC® System
Common Name	Physiological signal-based seizure monitoring system
Device Classification	Class II
Product Code & Regulation	POS; Non-EEG physiological signal-based seizure monitoring system; 21 CFR 882.1580
Review Panel	Neurodiagnostic Devices; Neurology

Predicate Device DEN140033

Manufacturer	Brain Sentinel, Inc.
Device Name	Brain Sentinel Monitoring and Alerting System
Regulation Name	Non-EEG physiological signal-based seizure monitoring system
De Novo Number	DEN140033
Product Code	POS
Regulation Number	21 CFR 882.1580
Device Classification	Class II

Subject Device Description

The SPEAC® System, formerly known as the Brain Sentinel® Monitoring and Alerting System (Predicate), is a physiological, surface electromyography (sEMG) monitor with or without alarms that records and stores data for review by a physician for characterization of seizure events.

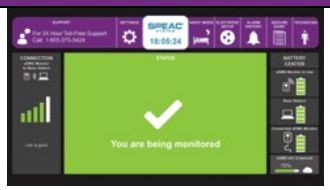
The System records sEMG data at 1,000 Hz and distributes physiological data. Data can be analyzed with an algorithm using the default threshold or by a modified threshold ordered by the physician.

The sEMG monitor is worn unilaterally on the belly of the patient's biceps and it analyzes for sEMG GTC seizures and provide local, remote, audible, and visual seizure alarms when a GTC Seizure pattern that may be associated with such seizures that are detected.

The SPEAC System provides sEMG recordings and audio data to physicians (or other trained healthcare professionals) for post-hoc review so that they may quantify and qualify the types of seizure events that their patients experience. Every 24 hours, the sEMG monitor is removed from the patient and replaced with the second sEMG Monitor on the opposite arm of the patient.

The sEMG that is removed after 24-hours is then attached to a Base Station. By connecting the sEMG Monitor to the Base Station, the monitor charges and the recorded data is downloaded to the Base Station. The recorded data is then automatically uploaded to Brain Sentinel's cloud-based storage unit, Data Distribution System (DDS), where they await review by a physician. All patient data is cyber-secured within Microsoft Azure which is FedRAMP certified. Below, Tables 1 and 2 list the functional and operational outputs designed to provide feedback to the patient and caregiver. These modes and outputs are no different than those which were cleared in the Predicate, DEN140033.

Table 1: Functional and Operational Outputs

SPEAC® System Functional Mode	Left LED Light	Right LED Light	Daily Monitoring Application Screen View	Description of the Functional Mode
Seizure Monitoring Mode ON	SOLID	SOLID		GTC Seizure Monitoring Mode: The patient is within the Wi-Fi covered area and being monitored for potential GTC seizure events. Seizure Alarms and Operational Alerts function in this mode.
Record Only Mode Activated	SOLID	SOLID		Record Only Mode allows the patient to leave the Wi-Fi covered area while recording sEMG data for subsequent review by the referring physician. Seizure Alarms and Operational Alerts do not function in Record Only Mode.
Seizure Alarm Mode	SOLID	FLASH		If a Seizure Alarm condition has been received, the Seizure Alarm is automatically activated. The patient or caregiver may select the CLICK TO SILENCE button to silence the audible part of the alarm for a duration of 5 minutes. A new Seizure Alarm screen will appear asking, *"Did the patient have a seizure?"* The User may respond by clicking one answer: YES, I Don't Know, or NO

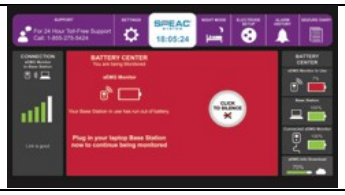
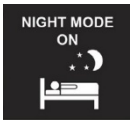
SPEAC® System Functional Mode	Left LED Light	Right LED Light	Daily Monitoring Application Screen View	Description of the Functional Mode
Loose Electrode Alert	FLASH	FLASH		The Electrode Patch is not making good contact with the patient's arm and needs to be replaced. Patient should follow the same steps for removing, replacing, and calibrating an Electrode Patch by applying gentle pressure to the sEMG Monitor for 2 minutes to allow for electrode adherence to the patient's skin. If the issue persists, ensure all electrode snaps are properly fastened to the sEMG Monitor before adhering to the patient.
sEMG Monitor Low Battery Alert	FLASH	FLASH		The battery is critically low on the sEMG Monitor in use and must be connected to the Laptop Base Station for recharging. Swap the low battery sEMG Monitor with the sEMG Monitor that is fully charged. Follow the same steps for removing, replacing, and calibrating an Electrode Patch.
Lost Connection Out of Wi-Fi Range Alert	SOLID	FLASH		The sEMG Monitor in use is outside the covered range and has lost wireless connection with the SPEAC System, notifying the patient to immediately return to a part of the Wi-Fi covered zone. If the router is working properly, 4 blue glowing Signal Strength LEDs will be visible. If the LEDs are not lit, unplug and replug the router to the electrical wall outlet. Wait 4 minutes for the Wi-Fi connection to be restored.

Table 2– SPEAC System Outputs Intended for Patients and Caregivers

SPEAC® System Operational Alert Condition	Application View	Description
Settings Button		Used to swap functional modes between GTC Seizure Monitoring Mode and Record Only Mode.
Night Mode Button		Used to help the patient sleep soundly since the Laptop Base Station display screen and lights on the sEMG Monitor may be dimmed. Users may click the **Night Mode button** to turn Night Mode ON.
Night Mode ON Button		Used to disable Night Mode setting and return the SPEAC System display screen to regular brightness. Users may alternate between Night Mode and Night Mode ON as often as necessary.
Electrode Setup Button		Used to initiate the Electrode Setup process every time a new Electrode Patch is placed on a patient. Daily calibration of a new Electrode Patch is required for using the System in GTC Seizure Monitoring Mode or Record Only Mode.
Alarm History Button		Used to display a list of all Seizure Alarms and Operational Alerts that have occurred during the prescribed monitoring period. Use the scroll bar to review the cumulative list. A new or existing Seizure Diary entry can be accessed from this list as well as using the Seizure Diary button noted below.

SPEAC® System Operational Alert Condition	Application View	Description
Seizure Diary Button		If the System sends a Seizure Alarm for a potential GTC Seizure event, a yellow exclamation point will appear over the **Seizure Diary button** to indicate a new Seizure Diary entry has been automatically created**.** Users may click this button to open the electronic form that will allow the patient or caregiver to record specific details about the event.
Wi-Fi-Status Indicator Bar		The Laptop Base Station serves as the control hub for the entire SPEAC System. The Wireless Router provides a communications link between the sEMG Monitor in use and the Laptop Base Station. The Wireless Router can communicate with the sEMG Monitor up to a 300-foot range (approximate). The **Wi-Fi Status Bars** indicate connection signal strength.

Intended Use/ Indications for Use

The SPEAC® System is indicated for use as an adjunct to seizure monitoring in adults in the home or healthcare facilities during periods of rest. The System records and stores surface electromyographic (sEMG) data for subsequent review by a trained healthcare professional.

The device is to be used on the belly of the biceps muscle to analyze sEMG signals that may be associated with generalized tonic-clonic (GTC) seizures. When sEMG signal patterns associated with a unilateral, appendicular, tonic extension that could be associated with a GTC seizure are detected, the SPEAC System sends adjunctive alarms to alert caregivers. Adjunctive alarms may be disabled by a physician order while continuing to record sEMG data for subsequent review.

Table 3: Non-Clinical Test Summary for the SPEAC® System in K182180

Test	FDA Recognition Number
IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) (3rd Edition), Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance	19-4
IEC 60601-1-2: 2014-02 (4th Edition), Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance, Collateral Standard, Electromagnetic Compatibility	19-8
IEC 60601-1-6: Medical electrical equipment – Part 1-6: general requirements for basic safety and essential performance – collateral standard: usability	5-89
IEC 60601-1-8: Medical electrical equipment – Part 1-8: general requirements for basic safety and essential performance – collateral standard: general requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems	5-76

Test	FDA Recognition Number
IEC 60601-1-11: 2010 (1st Edition) General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.	This version is no longer FDA recognized but the design changes to the subject device do not require additional testing. All design changes are minor and outside the scope of this test (e.g., electrode patch testing).
IEC 60601-2-40: 2016 (2nd Edition) Medical electrical equipment – Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment	N/A Not an FDA recognized standard; This testing has been voluntarily performed by the company to demonstrate performance and validate the system.
Biocompatibility Testing ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process; Fourth edition	2-220
ISO 10993-5 Third edition 2009-06-01: Biological evaluation of medical devices – Part 5: Tests for vitro cytotoxicity	2-245
ISO 10993-10 Third Edition 2010-08-01: Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	2-174
Shipping and Distribution Test (ISTA 3A)	5-110
Software Verification and Validation	N/A
Performance Validation of SPEAC System	N/A

Table 4: Comparison of Technological Characteristics to Predicate Device

Characteristic	K182180 Subject Device SPEAC® System	DEN140033 Predicate Device Brain Sentinel® Monitoring and Alerting System	Comment
Indications for Use	The SPEAC® System is indicated for use as an adjunct to seizure monitoring in adults in the home or healthcare facilities during periods of rest. The System records and stores surface electromyographic (sEMG) data for subsequent review by a trained healthcare professional. The device is to be used on the belly of the biceps muscle to analyze sEMG signals that may be associated with generalized tonic-clonic (GTC) seizures. When sEMG signal patterns associated with a unilateral, appendicular, tonic extension that could be associated with a GTC seizure are detected, the SPEAC System sends adjunctive alarms to alert caregivers. Adjunctive alarms may be disabled by a physician order while continuing to record sEMG data for subsequent review. (Rx-only)	The Brain Sentinel Monitoring and Alerting System is indicated for use as an adjunct to seizure monitoring in adults in the home or healthcare facilities during periods of rest. The device is to be used on the belly of the biceps muscle to analyze surface electromyographs (sEMG) signals that may be associated with generalized tonic-clonic (GTC) seizures and to provide an alarm to alert caregivers of unilateral, appendicular, tonic extension that could be associated with a GTC seizure. The System records and stores sEMG data for subsequent review by a trained healthcare professional. (Rx-only)	Similar; The indications have been modified to clarify the intended use by specifically stating the sEMG recording and alarm controls that are available to the users. These features were cleared in DEN140033.

Characteristic	K182180 Subject Device SPEAC® System	DEN140033 Predicate Device Brain Sentinel® Monitoring and Alerting System	Comment
Classification	Class II 21 CFR 882.1580 Non-EEG physiological signal-based seizure monitoring system	Class II 21 CFR 882.1580 Non-EEG physiological signal-based seizure monitoring system	Same; No change
Product Code	POS	POS	Same; No change
Major System Components – sEMG Monitor			
Principle of Operation	sEMG signal, sampled at the rate of 1000 Hz, from the biceps brachii are processed by a proprietary algorithm to identify sustained sEMG contraction patterns—during the tonic phase and early transition to the clonic phase—that are pathognomonic of GTC seizures.	sEMG signal, sampled at the rate of 1000 Hz, from the biceps brachii are processed by a proprietary algorithm to identify sustained sEMG contraction patterns—during the tonic phase and early transition to the clonic phase—that are pathognomonic of GTC seizures.	Same; No change
Dimensions	3.44” x 2.34” x 1.33” (H x W x D)	3.44” x 2.34” x 1.33” (H x W x D)	Same; No change
Mass	127 g.	127 g.	Same; No change
Physical Controls	Power On/Off Button (Manual) Alarm Button Cancel Button	Power On/Off Button (Manual) Alarm Button Cancel Button	Same; No change

Characteristic	K182180 Subject Device SPEAC® System	DEN140033 Predicate Device Brain Sentinel® Monitoring and Alerting System	Comment
sEMG sampling rate	1,000 Hz	1,000 Hz	Same; No change
sEMG Frequency Bands of Interest	30-40 Hz, 130-240 Hz, and 300-400 Hz	30-40 Hz, 130-240 Hz, and 300-400 Hz	Same; No change
Type of Monitoring	Unilateral, appendicular, tonic extension that could be associated with a GTC seizure	Unilateral, appendicular, tonic extension that could be associated with a GTC seizure	Same; No change
Default Alarm Threshold	135	135	Same; No change
sEMG Monitor Power	Rechargeable Battery; 2200 mAh (Li-Polymer)	Rechargeable Battery; 2200 mAh (Li-Polymer)	Same; No change
Laptop Base Station			
Model	COTS Laptop	COTS Laptop	Same; No change
Input Power	115/230 VAC 50/60 Hz	115/230 VAC 50/60 Hz	Same; No Change
Graphical User Interface	Laptop Base Station	Laptop Base Station	Same; No change

Characteristic	K182180 Subject Device SPEAC® System	DEN140033 Predicate Device Brain Sentinel® Monitoring and Alerting System	Comment
Software Controls	Alert Mode (adjunctive seizure monitoring and sEMG recording), Record Only (sEMG recording)	Alert Mode (adjunctive seizure monitoring and sEMG recording)	Similar; sEMG recording was previously cleared but in this 510(k), the physician can now disable the alarm so that they device is recording only and therefore does not alarm.
sEMG Electrode			
sEMG Electrode	sEMG Electrode	sEMG Electrode	Similar; The electrode patch has increased in surface area to improve the comfort to the user in wearing the device while maintaining patch integrity. Electrode testing was performed to validate the new electrode.
Network Connection			
Cellular Router	Cradlepoint Router	Cradlepoint Router	Same; No change.
Recharging Accessories			
sEMG Monitor Recharging Accessories	USB – Micro-USB	USB – Micro-USB	Same; No change.

Characteristic	K182180 Subject Device SPEAC® System	DEN140033 Predicate Device Brain Sentinel® Monitoring and Alerting System	Comment
Laptop Base Station Recharging Accessories	12V / 1.5A	12V / 1.5A	Same; No change.
Arm Strap			
sEMG Monitor Arm Strap	Black Spandex Arm Strap	Black Spandex Arm Strap	Same; No change.
MDDS			
Medical Device Data Systems	Physician Portal (SPEAC2ME®)	Physician Portal (SPEAC2ME®)	Similar; The portal has been upgraded to allow physicians to disable the alert mode for record only mode.
Limitations			
Warnings & Limitations	• The System is available by prescription only from a physician or properly licensed practitioner. • The System should not be used as a standalone monitor for monitoring seizures and is not intended to be used during physical activity. • The device is not a seizure detection device.	• For prescription use only. • The device is not a GTC seizure detection device and should not be used to guide medical therapy decisions. • The safety and effectiveness of the Brain Sentinel® Monitoring and Alerting System has not been established in monitoring sEMG	Similar with modifications to align and be consistent with the indications for use (i.e., recording mode) and to better inform users and patients on appropriate use of the subject device.

Characteristic	K182180 Subject Device SPEAC® System	DEN140033 Predicate Device Brain Sentinel® Monitoring and Alerting System	Comment
	• The System alarms are not for standalone use and should not be used to guide medical therapy decisions. • The System has not been demonstrated to affect any clinical outcome such as status epilepticus, brain damage, or death following a GTC seizure. • The System does not predict sEMG signals that may be associated with GTC seizures. The device provides an alert from -30.82 – 25.06 seconds, with an average of 5.34 seconds (SEM ± 2.86), following the onset of sEMG activity that may be associated with a GTC seizure. • The System does not predict seizure onset. • The safety and effectiveness of the System has not been established in pediatric populations.	signals that may be associated with seizures other than the GTCS. • The safety and effectiveness of the Brain Sentinel® Monitoring and Alerting System has not been established in pediatric populations. • The device is not intended to be used as a stand-alone monitoring device. • The device is not intended to be used during physical activity. • This device does not predict seizure onset. • PLEASE REFER TO THE LABELING FOR A MORE COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.	

Characteristic	K182180 Subject Device SPEAC® System	DEN140033 Predicate Device Brain Sentinel® Monitoring and Alerting System	Comment
	• The System has not been tested in the home environment. • The safety and effectiveness of the SPEAC System has not been established in monitoring sEMG signals that may be associated with seizures other than the GTC seizure. • The sEMG Electrode Patch may result in skin irritation that may lead to hypersensitivity in some individuals. • Never allow the sEMG Monitor to be submerged in any liquid. Contact Brain Sentinel if the sEMG Monitor or Laptop Base Station has been submerged. Do not attempt to use or service a sEMG Monitor or Base Station that has been submerged. • Only Brain Sentinel authorized equipment should be used with or connected to the SPEAC System. • The Laptop Base Station is optimized for the functions performed by the SPEAC System. Do not install applications, uninstall		

Characteristic	K182180 Subject Device SPEAC® System	DEN140033 Predicate Device Brain Sentinel® Monitoring and Alerting System	Comment
	applications, or alter the configuration or environment variables of this.		

Conclusion

The SPEAC® System has undergone minor hardware and software changes to improve user needs and to better communicate the intended use in the labeling and indications for use. These changes include: a modified indication for use statement, an increase in surface area of the electrode patch to improve the comfort to the patient but maintaining patch integrity, and the housing atop the patch. Verification and validations were performed on the electrode patch along with usability testing, performance testing, accelerated aging, ship testing, and biocompatibility testing was performed to ensure intended use functionality remains and the product is substantially equivalency to the current Predicate. Minor updates to the software were made to improve the user experience and keep the technology updated with current technological infrastructure requirements. Verification and validation were performed to ensure intended use was maintained and the product is substantially equivalency to the predicate. The sEMG based seizure detection algorithm is identical to the predicate. Based on device characteristics, indications for use, and testing submitted to support the submission, the SPEAC® System is substantially equivalent to the predicate device (Brain Sentinel Monitoring and Alerting System, manufactured by Brain Sentinel, Inc.).